James R. Condo (#005867) – jcondo@swlaw.com
Amanda C. Sheridan (#027360) – sheridan@swlaw.com
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
Telephone: 602.382.6000

Richard B. North, Jr. – richard.north@nelsonmullins.com
Georgia Bar No. 545599 – (admitted *pro hac vice*)
Matthew B. Lerner – richard.north@nelsonmullins.com
Georgia Bar No. 446986 – (admitted *pro hac vice*)
NELSON MULLINS RILEY & SCARBOROUGH LLP
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000

Attorneys for Defendants

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. 2:15-MD-02641-DGC

DEFENDANTS' REPLY IN SUPPORT OF ITS MOTION FOR PROTECTIVE ORDER REGARDING REPORT OF DR. JOHN LEHMANN

The factual and legal arguments that the plaintiffs raise in their response briefing are unpersuasive, and Bard's Motion for Protective Order should be granted in full:

- The plaintiffs argue that Dr. Lehmann's report was prepared in the ordinary course of business, but every court to have considered the *Alexander* evidentiary hearing materials has rejected this same argument for good reason. Sworn testimony from Dr. Lehmann and the Assistant General Counsel who hired him rebut the argument, and the argument relies on pieced-together circumstantial evidence that does not stand up to scrutiny.
- The plaintiffs' numerous waiver arguments are unsupported. The plaintiffs' "sword and shield" waiver argument fails to identify how Bard used Dr. Lehmann's report during this litigation as a sword. Their crime-fraud argument fails because it is based principally on assertions of counsel and a handful of documents taken out of context. Finally, the plaintiffs' argument that Bard waived

its work-product claim by not objecting on confidentiality grounds is factually inaccurate because Bard did object on these grounds, and the plaintiffs cite no law that supports their argument.

- The plaintiffs argue that they have substantial need for Dr. Lehmann's report, but every court to have addressed this argument has rejected it. The plaintiffs admit that they have the same data that Dr. Lehmann had, and that they have previously hired an expert purportedly to perform the same analysis that Dr. Lehmann performed. Their other substantial need arguments are speculative or inaccurate because they already have the material they say only Dr. Lehmann's report can provide.
- The plaintiffs cite no law to support a request for substantial additional discovery about the creation of a single document, and Bard has not found any supportive law either. And the current record to resolve Bard's work-product assertion is more robust than the record in any other case that either party has found.[1]

ARGUMENT

1. Dr. Lehmann's Report was prepared in anticipation of litigation, not in the ordinary course of business.

The six principal points that the plaintiffs make in arguing that Dr. Lehmann's report was prepared in the ordinary course of business do not hold up to scrutiny. Thus for good reason, every court that has considered the *Alexander* evidentiary hearing testimony and exhibits has rejected the plaintiffs' "ordinary course of business" argument, including three courts that applied the narrowest work-product test in the country, not the broader "because of" test applied in the Ninth Circuit.

First, the plaintiffs claim that Dr. Lehmann's report was required by federal statutes and regulations. The plaintiffs cite various U.S. Code and C.F.R. sections to claim that federal law required the creation of Dr. Lehmann's report. (Pl. Resp. (Doc.

[1] The parties appear to agree that the Court's ruling should not affect cases where the issue has already been decided. Thus, Bard will not address the plaintiffs' argument any further in its reply.

Snell & Wilmer L.L.P. LAW OFFICES One Arizona Center, 400 E. Van Buren, Suite 1900 Phoenix, Arizona 85004-2202 602.382.6000

379), at 5-6.) The plaintiffs also cite Bard's Regulatory Affairs Manual (Ex. 12 to Pl. Resp.) to suggest that Dr. Lehmann's report was part of Bard's regulatory obligations. (Pl. Resp. (Doc. 379), at 13-14.) But none of the statutes, regulations, or internal Bard policy that the plaintiffs cite have anything to do with requiring the kind of extensive analysis of the MAUDE database and bench testing found in Dr. Lehmann's report.[2]

The plaintiffs cite Dr. Ciavarella's testimony that a company has a responsibility to analyze MAUDE database trends. (*Id.* at 6, 19.) Dr. Ciavarella, however, is not a lawyer, and the plaintiffs have been unable to identify a statute or regulation requiring such MAUDE database trending analysis. Moreover, Dr. Lehmann did not perform MAUDE trending analysis in his report. Rather, he attempted to analyze particular adverse event rates, compared those rates across all IVC filters, and compared the rates to Bard's bench testing—this is a significantly different than "trending of the MAUDE database." (Ex. S to Mot., Lehmann Report, at BPVE-01-01019788.)

Finally, if the plaintiffs' argument was true that federal law required the preparation of Dr. Lehmann's report, then there would be many "Lehmann reports" throughout the roughly decade-worth of documents that Bard has produced to date. But among these millions of pages of documents, the plaintiffs can identify no analysis of similar size and scope.[3]

---

[2] 21 U.S.C. section 351, which the plaintiffs cite, simply defines adulterated drugs and devices; 21 U.S.C. section 321(n) defines the scope of a "misbranded" article; 21 U.S.C. section 352(a)(f)(1), (2) do not exist, but section 352 as a whole defines when a drug or device shall be deemed "misbranded"; 21 U.S.C. section 331(a) and (b) merely prohibit adulterated or misbranded devices; 21 U.S.C. section 360(e) gives the FDA the authority to establish a uniform system for identifying medical devices; 21 C.F.R. section 820.198 requires manufacturers to maintain a complaint-handling system, evaluate individual complaint files, and report certain complaints to the FDA, all of which Bard does; 21 C.F.R. section 803.1 generally defines the scope of Part 803; 21 C.F.R. section 803 establishes reporting adverse event reporting requirements for individual adverse events; and Bard's Regulatory Affairs Manual provides a guiding document for the development and implementation of a "remedial action plan," which is a proposed action plan for dealing with potential product problems. None of these items even hints at, much less requires, any type of analysis like what appears in Dr. Lehmann's report.

[3] Because Bard was not required to compile Dr. Lehmann's report to comply with federal regulations, the plaintiffs' reliance on *U.S. v. Richey*, 632 F.3d 559 (9th Cir. 2011), where the document at issue was required by law to be attached to a federal tax return, is misplaced. (Pl. Resp. (Doc. 379), at 13, 19.)

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000

Second, the plaintiffs claim that Dr. Lehmann was working on the analysis that would be included in his report throughout 2004. (Id. at 2, 6-10.) In their entire response brief, the last document that the plaintiffs cite where Dr. Lehmann is either the author or recipient is the April 2004 Health Hazard Evaluation ("HHE"). There is a good reason for the eight-month gap in the documents that the plaintiffs cite between the April 2004 HHE and the December 2004 report: Dr. Lehmann was serving as Bard's interim medical director in early 2004 (which is why he was the author of several HHEs that the plaintiffs cite and part of the Crisis Communication Team), but a permanent medical director, Dr. David Ciavarella, was hired in May 2004. (D. Ciavarella Dep. Tr., *Giordano v. C. R. Bard, Inc.*, 13:12-14; 53:21 to 54:14, Nov. 12, 2013, attached as Exhibit A; Ex. Q to Mot., *Alexander* Hr'g Tr., 87:2-9 (Dr. Lehmann testifying that he was acting medical director for Bard from the fall of 2003 to late spring 2004 when Dr. Ciavarella was hired).) Thus, in May 2004, Dr. Lehmann's work as interim medical director and with Bard's Recovery Filter basically stopped other than "occasional contact" with Dr. Ciavarella who was new to the job and was taking over tasks that Dr. Lehmann had performed. (Ex. Q to Mot., *Alexander* Hr'g Tr., 88:9 to 89:6.) This explains why the plaintiffs cite no documents involving Dr. Lehmann after April 2004.

Moreover, the plaintiffs' argument is based on a total misreading of the documents they cite, it ignores sworn testimony discussed throughout Bard's Motion, and it lacks reams of corroborating analysis that should exist if the plaintiffs are right.

Misreading/Omission of Documents	**Facts**
The plaintiffs argue that in March 2004, Dr. Lehmann had performed "the very same analysis" contained in his later December 2004 report as part of an HHE. (Pl. Resp. (Doc. 379), at 2, citing Exhibit 1.) And in March 2004 "Dr. Lehmann was already involved in the review and	The language of the March 2004 HHE neither discusses nor suggests that Dr. Lehmann performed a complex analysis of rates of migration for all IVC filters, comparative risk estimates between IVC filters, or a comparison of the results to Bard's bench testing of the filters (i.e., "the very same analysis"), which is what he undertook to write the December 2004 report.[4]

[4] The March 2004 HHE provides, "[t]here have been 3 migrations of the Recovery VC Filter in which the device ended up in or near the heart, with one fatality, in an estimated 6,402 sales through March 2, 2004, for a rate of 0.05%. . . . These types of adverse events

analysis of the FDA MAUDE data to compare Bard's failure rates and modes to those of its competitors." (*Id.* at 8, citing nothing to support the proposition.)	
The plaintiffs claim that "the gathering, analysis, and use of that [MAUDE analysis] information went on throughout 2004." (Pl. Resp. (Doc. 379), at 2.)	The plaintiffs cite nothing to support this statement, and the plaintiffs' bald assertion is incorrect.
Dr. Lehmann was part of a "Crisis Communication Team" in April 2004 regarding an adverse event with the Recovery Filter, and Dr. Lehmann mentioned in an e-mail that "[c]omparison with other filters is problematic in many ways," which shows that he was performing his MAUDE database analysis in April. (Pl. Resp. (Doc. 379), at 7-8, citing Exhibit 2.)	Basic epidemiological principles provide that there are many known biases and limitations with attempts to reliably generate and compare adverse event rates. *See, e.g.*, *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* (3d ed. 2011); FDA MAUDE Database Disclaimer,[5] attached as Exhibit B ("MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices."). Merely stating that comparison with other filters is problematic does not denote that Dr. Lehmann had actually done a comparison, and the plaintiffs have not cited any comparison that Dr. Lehmann purportedly had done at this time.
Another HHE that Dr. Lehmann wrote in April 2004 "would have required him to conduct a comparative analysis of Bard's Recovery filter as against the filters of its competitors." (Pl. Resp. (Doc. 379), at 8.)	The plaintiffs do not cite the actual HHE to support their claim. The actual HHE, however, contains very similar language as the March 2004 HHE; as discussed above, such language does not show or suggest that Dr. Lehmann undertook analysis even remotely similar to what appeared in his December 2004 report. (J. Lehmann, Recover Filter Migration HHE, Apr. 27, 2004, BPV-17-01-00153179, attached as Exhibit C.)
Dr. Ciavarella testified that "Dr. Lehmann was engaged to analyze the MAUDE data . . . ." (Pl. Resp. (Doc. 379), at 9, citing Exhibit 5.)	Although the context of the plaintiffs' statement suggests that Dr. Ciavarella was referring to early 2004 in his response, the actual testimony that they cite was in response the following question: "Well, eventually didn't Dr. Lehmann take some of this data – and I don't know what time period it was – the MAUDE data, and determine that there was a statistically significant increased risk . . . ?" (Ex. 5 to Pl. Resp.) Clearly, neither the questioner (who is a signatory to the

of adverse events occur with all known types of vena cava filters, and are extensively reported in the medical literature." (Ex. 1 to Pl. Resp., at BPVE-01-00510992.) The HHE continues, "[c]omparative attempts to assess similar events via the MAUDE database do not yield reliable quantitative estimates . . . [h]owever, it is clear that since the MAUDE database has been kept, numerous instances of vena cava filters migrating to the heart with both fatal and nonfatal outcomes have been reported." (*Id.*)

[5] *At* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm.

Snell & Wilmer L.L.P. LAW OFFICES One Arizona Center, 400 E. Van Buren, Suite 1900 Phoenix, Arizona 85004-2202 602.382.6000

	plaintiffs' response) nor Dr. Ciavarella were referring to early 2004—in fact, Dr. Ciavarella did not start working at Bard until May 2004.

Finally, if the plaintiffs' theory was correct that Dr. Lehmann was conducting his analysis of the MAUDE data and bench testing data throughout 2004, then there would be reams of corroborating analysis and communication about it throughout 2004. But the plaintiffs have not identified anything to this effect. The reason, as detailed in Bard's Motion, is because Dr. Lehmann did not undertake this analysis until November 2004 when he was hired directly by Bard's Law Department.

Third, the plaintiffs claim that Bard's Law Department made "an eleventh hour attempt to cover up Dr. Lehmann's findings." (Pl. Resp. (Doc. 379), at 3, 9.) The plaintiffs argue that the March and April 2004 HHEs and an April 2004 e-mail from Dr. Lehmann concerning the Crisis Communication Team are proof that Dr. Lehmann's "review and analysis of the FDA MAUDE information . . . was producing dramatically bad results for Bard." (*Id.* at 9.) Plaintiffs continue, "faced with an upcoming report that would compile this bad information in a summary format, Bard's legal department decided to make an eleventh-hour attempt to cover up Dr. Lehmann's findings – signing him to a 'consulting agreement' with the legal department to do the work and analysis he was already performing." (*Id.*)

As discussed above, the HHEs and e-mail from Dr. Lehmann say nothing about a complicated MAUDE database analysis, comparison of rates across different IVC filters, or bench testing analysis. The plaintiffs cite no documents for their assertion that Dr. Lehmann's analysis in two HHEs from early 2004 "was producing dramatically bad results for Bard." And the plaintiffs cite no documents that Bard would be "faced with an upcoming report" or that the results of the analysis would be "bad."[6] Citing only a December 2004 draft remedial action plan, which says that Dr. Lehmann "was

[6] Indeed, because the last document that the plaintiffs cite regarding Dr. Lehmann is from April 2004, the plaintiffs' "eleventh hour cover up" theory does not fit the timeline of the documents that they cite.

Snell & Wilmer L.L.P. LAW OFFICES One Arizona Center, 400 E. Van Buren, Suite 1900 Phoenix, Arizona 85004-2202 602.382.6000

commissioned by Corporate Senior Management to provide an independent study," the plaintiffs accuse Bard's law department of "an eleventh hour cover up." (*Id.*) In sworn testimony, however, Donna Passero directly addressed this issue:

> Q. Ms. Passero, there have been some allegations in this litigation that this report was commissioned by the Law Department simply to maintain secrecy regarding the report. Do you believe that to be true?
>
> A. No, not at all. . . . I do know that the other responsible individuals, whether that was at a corporate level or at the BPV level, were retaining him to do reports also. So there would be no need for us to hide it. They had their own report to do it. And I – it seems a little unseemly. I wouldn't do something like that just to hide information. This was for us to evaluate the – the potential litigation that was – that was believed was going to happen and, from what I understand, has happened.

(Ex. Q to Mot., *Alexander* Hr'g Tr., 31:19 to 32:15.) Thus, the language in the Remedial Action plan is clearly an error.

Fourth, the plaintiffs claim that Dr. Lehmann's findings were used for numerous business purposes, including several days before its finalization in preparing a Remedial Action Plan[7] *and an HHE*.[8] (Pl. Resp. (Doc. 379), at 9-10.) Bard does not deny that Dr. Lehmann's report was used, in part, for a business purpose. Any responsible company that received potentially concerning information about its product would put together an action plan and investigate the issue. As Donna Passero testified, the Law Department "can't sit on information that can be harmful to the public, to patients. So I gave it [Dr. Lehmann's report] to people who would know what to do with that information . . . ." (Ex. Q to Mot., *Alexander* Hr'g Tr., 31:13-18.) The relevant inquiry for assessing whether a document is work product, however, is not "how did the company use the document after it was created?"; rather, the relevant inquiry is "was the document created because of the

[7] The Court should note that the plaintiffs reference a December 9, 2004, Remedial Action Plan (Pl. Resp. (Doc. 379), at 9, citing Exhibit 3) and a January 2005 Remedial Action Plan (*id.* at 10, citing Exhibit 13) to suggest that Dr. Lehmann's report was used to assist in the preparation of two different remedial action plans, but the December 9 document is actually a draft of the final January plan, which is apparent by same plan identification number listed on the documents, SPA-04-12-01.

[8] The plaintiffs also argue that Bard's public relations firm made "liberal use" of Dr. Lehmann's report, which is false, and the plaintiffs cite nothing to support this allegation. (Pl. Resp. (Doc. 379), at 15.)

Snell & Wilmer L.L.P. LAW OFFICES One Arizona Center, 400 E. Van Buren, Suite 1900 Phoenix, Arizona 85004-2202 602.382.6000

prospect of litigation?" *United States v. Richey*, 632 F.3d 559, 568 (9th Cir. 2011). For this reason, four courts that have evaluated the plaintiffs' argument have found that the argument suffers from a "chronological problem." *See, e.g.*, *Peterson v. C. R. Bard, Inc.*, No. 13-528-JJB-RLB (M.D. La. Mar. 3, 2015), at 12, attached as Exhibit D (citing the other three cases and noting that the argument "wrongly focuses on subsequent uses of the Lehmann Report, as opposed to the initial purpose for which the document was created"). As detailed in Bard's Motion, ample evidence proves that Dr. Lehmann's report was prepared in anticipation of litigation, and Donna Passero testified that she would not have retained Dr. Lehmann to prepare his report in December 2004 if there had not been the prospect of litigation. (Ex. Q to Mot., *Alexander* Hr'g Tr., 32:16-19.) The fact that Dr. Lehmann's report was later used, in part, for a business purpose is irrelevant.

The plaintiffs also argue that Dr. Lehmann's report was created in the ordinary course of business because the report is "a straight-forward statistical analysis" with no mental impressions, strategy, or reference to litigation. (Pl. Resp. (Doc. 379), at 3, 10.) And they claim that Dr. Lehmann's report was not used for any litigation purpose. (*Id.* at 15.) Every page of Dr. Lehmann's report, however, contains a header that reads "Privileged and confidential Attorney work product -- Pursuant to contract" (Ex. S to Mot., Lehmann Report); Dr. Lehmann's contract says that he was being retained "in anticipation of litigation" (Ex. R. to Mot, Lehmann Contract, at 1); and Donna Passero testified that she needed Dr. Lehmann's analysis to provide legal advice to Bard (Ex. Q to Mot., *Alexander* Hr'g Tr., 25:10 to 26:13).[9]

[9] Additionally, the plaintiffs' contentions about the report not referencing litigation could be true of many reports prepared by non-lawyer consultants at the direction of counsel and in anticipation of litigation. *See, e.g.*, *Bickler v. Senior Lifestyle Corp.*, 266 F.R.D. 379, 381 (D. Ariz. 2010) (summaries of interviews conducted by non-lawyers and witness statements obtained by non-lawyers about an accident were protected work product); *In re Grand Jury Subpoena (Torf)*, 357 F.3d 900 (9th Cir. 2004) (documents about the disposal of waste material created by an environmental consultant on a cleanup project at Ponderosa Paint were protected work product). Nothing in these opinions suggests that the documents at issue on their face revealed a litigation purpose. Rather, the courts homed in on the context of the documents' *creation* to conclude that they were prepared because of litigation. The creation inquiry also reveals the plaintiffs' misplaced reliance on *Soeder v. General Dynamics Corp.*, 90 F.R.D. 253, 255 (D. Nev. 1980) (finding that the report at issue was not work product largely because both parties conceded that similar

Snell & Wilmer L.L.P. LAW OFFICES One Arizona Center, 400 E. Van Buren, Suite 1900 Phoenix, Arizona 85004-2202 602.382.6000

Fifth, the plaintiffs argue that litigation was not "imminent" until Bard instituted a litigation hold in December 2004. (Pl. Resp. (Doc. 379), at 16.) The plaintiffs' argument applies a heightened standard for work-product protection. The Ninth Circuit requires only that a document be prepared because of the "prospect of litigation," not that litigation be "imminent." *U.S. v. Richey*, 632 F.3d 559, 568 (9th Cir. 2011). Moreover, Donna Passero provided sworn testimony that she hired Dr. Lehmann to prepare his report because she anticipated litigation. (Ex. Q to Mot., *Alexander* Hr'g Tr., 32:16-19). Finally, before Dr. Lehmann was hired to write his report, Bard had received several threats of litigation and notified its insurer. (Exs. B, D, E, G to Mot.) Thus, Bard has submitted unrebutted evidence that it subjectively and objectively anticipated "the prospect of litigation" before hiring Dr. Lehmann to prepare his report.

Sixth, the plaintiffs argue that Judge Jones in Phillips ruled that Dr. Lehmann's report was not work product and that he is the only judge who "has had the benefit of a full evaluation at trial of the evidence and course of dealings of Dr. Lehmann's history." (Pl. Resp. (Doc. 379), at 10.) As noted in Bard's Motion, however, Judge Jones declined to consider any of the *Alexander* evidentiary hearing testimony or exhibits that Bard has submitted to this Court; he declined to consider the rulings of the courts that did evaluate the evidence; he declined to consider any briefing on the Ninth Circuit's work-product standard; he overruled, without considering, the detailed and lengthy ruling of his Magistrate Judge regarding Dr. Lehmann's report that has been cited with approval by several other courts deciding the issue (Ex. Y to Mot.); and Judge Jones only heard the plaintiff's side of the story given the juncture of the trial when the issue arose. (*See* Mot. (Doc. 306), at 16.) Moreover, the Court should note that although the plaintiffs portray the *Phillips* trial as full of testimony and exhibits about the creation of Dr. Lehmann's

---

reports were routinely created after every accident regardless of anticipated litigation) and *Marceau v. I.B.E.W.*, 246 F.R.D. 610, 614 (D. Ariz. 2007) (finding that an audit was not work product when it stated that it was created to study and propose solutions for ongoing management issues facing the company and would have been created regardless of potential litigation). Here, Dr. Lehmann's report is the only report of its size and scope, and Donna Passero specifically testified that it would not have been created unless Bard had anticipated litigation. (Ex. Q to Mot., *Alexander* Hr'g Tr., 32:16-19).

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000

report, in fact the work-product issue arose suddenly and unexpectedly when the plaintiff attempted to introduce Dr. Lehmann's report as an exhibit. Thus, rather than the lengthy, considered ruling that the plaintiffs portray, the reality is that Judge Jones made a ruling on the admissibility of Dr. Lehmann's report from the bench, mid-trial, as one of many such bench rulings.

2. Bard did not waive the work product protection.

a. Sword and shield waiver is inapplicable to Dr. Lehmann's report.

"Sword and shield" waiver only occurs when a party produces beneficial work-product documents, while withholding other harmful work-product documents. *Torres v. Goddard*, No. CV 06-2482, 2010 WL 3023272, at *6 (D. Ariz. July 30, 2010); *Verizon Cal. Inc. v. Ronald A. Katz Tech. Licensing, L.P.*, 266 F. Supp. 2d 1144, 1148 (C.D. Cal. 2003) ("When a party raises a claim which in fairness requires disclosure of the protected communications, [these protections] may be implicitly waived.") (citation omitted). In the history of this litigation, however, Bard has never used Dr. Lehmann's report as either a sword or a shield. *See Bickler v. Senior Lifestyle Corp.*, 266 F.R.D. 379, 383 n.2 (D. Ariz. 2010) (rejecting sword and shield argument where the defendant stated that it did not intend to use the work-product material in the litigation).

The plaintiffs also claim that in non-protected documents, Bard noted that a component of Dr. Lehmann's analysis involved "bariatric patients" and that this phrase somehow is a "sword." (Pl. Resp. (Doc. 379), at 21.) But they do not say why or how "bariatric patients" is a sword, and Bard has never raised that issue in these cases.

Finally, the plaintiffs claim that "Bard told the FDA and the medical community that the Recovery failed at the same rate as the competition models while knowing from the Report that this was not true," and the plaintiffs claim that they need Dr. Lehmann's report to "correct this misapprehension." (*Id.* at 21-22.) Any such alleged representations to the FDA and the medical community, however, would not be a "sword" of selectively disclosed work product from Dr. Lehmann's report. And the plaintiffs have many sources of readily available substantially equivalent information that they can use to try to

Snell & Wilmer L.L.P. LAW OFFICES One Arizona Center, 400 E. Van Buren, Suite 1900 Phoenix, Arizona 85004-2202 602.382.6000

disprove any such alleged representations, such that they do not have substantial need for Dr. Lehmann's report.

b. The plaintiffs cannot meet their burden of proof that the crime-fraud exception applies to Dr. Lehmann's report.

The crime-fraud exception to the work-product doctrine applies only when the client consults an attorney to further the commission of a crime or fraud. *In re Grand Jury Proceedings*, 87 F.3d 377, 381 (9th Cir. 1996). The plaintiffs must prove by a preponderance of the evidence[10] that (1) Bard "was engaged in or planning a criminal or fraudulent scheme when it sought the advice of counsel to further the scheme." *Id.* (quotation omitted), and (2) Dr. Lehmann's report was "'sufficiently related to' and w[as] made '*in furtherance of* [the] intended, or present, continuing illegality.'" *In re Napster*, 479 F.3d at 1090 (emphasis and alteration in original). The plaintiffs have fallen well short of their burden.

The plaintiffs have not proven by a preponderance of the evidence that Bard was involved in a fraud. The plaintiffs allege that Bard was involved in a seven-year-long "scheme to sell its dangerous products to unsuspecting doctors and patients: its cover up of adverse testing, injuries, and deaths associated with its filters." (Pl. Resp. (Doc. 379), at 24.) The plaintiffs, however, have cited nothing to support their claim that Bard's actions amounted to a "scheme" or a "cover up." Rather, the plaintiffs' allegations principally rest on assertions of counsel to link together a couple of documents ranging from 2004 to 2011 that are taken significantly out of context.[11] For instance, the plaintiffs claim that

[10] Although the plaintiffs argue that they need only prove "reasonable cause" of unlawful activity, citing *In re Grand Jury Proceedings*, 87 F.3d 377 (9th Cir. 1996), the Ninth Circuit later adopted a preponderance of the evidence standard in *In re Napster, Inc. Copyright Litig.*, 479 F.3d 1078, 1095 (9th Cir. 2007), *abrogated on other grounds, Mohawk Indus., Inc. v. Carpenter*, 130 S. Ct. 599 (2009).

[11] The plaintiffs also make spurious references to a guilty plea that occurred more than 20 years ago, arose from a different division of Bard (which is also a division that Bard no longer owns), concerned a different product than at issue in this case, involved none of the same employees that were involved with Bard's IVC filters, and was based on conduct that occurred almost 30 years ago. (Pl. Resp. (Doc. 379), at 23 n.15.) The plaintiffs also refer to other MDLs involving Bard products, and falsely assert that they are proof of "Bard's decision to put other dangerously unsafe products on the marketplace." (*Id.*) Finally, the plaintiffs suggest that a previous settlement is proof of guilt in referencing a

Snell & Wilmer L.L.P. LAW OFFICES One Arizona Center, 400 E. Van Buren, Suite 1900 Phoenix, Arizona 85004-2202 602.382.6000

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000

Bard formed a Crisis Communication Team in early 2004 in response to "the abysmal safety records of the Recovery Filter" (*Id*. at 24). In fact, however, the Team was formed to address two serious patient adverse events out of 8500 Recovery Filters sold where the Recovery Filter had migrated to the heart (*see* Ex. 11 to Pl. Resp., at BPV-17-01-00164737-38, 773), and both events were reported to the FDA. (Ex. H to Mot., at BPV-COMP-00004524 (noting event report to the FDA); Ex. I to Mot., at BPV-COMP-00000176 (same).) As of April 2004 when the Crisis Communications Team met, the reported rate of migrations to the heart for the Recovery Filter was 0.05% (4/8500 filters sold) (Ex. C, HHE, Apr. 27, 2004), which was well below the 2-5% rate reported in the medical literature for such migrations concerning all IVC filters. (Grassi, *Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism*, 12 J. Vascular Interventional Radiology 137 (2001), attached as Exhibit E.)

The plaintiffs also cite documents for propositions that adverse event rates for the Recovery Filter were "28 times higher," "4.6, 4.4, 4.1, and 5.3" times higher, and "55 times higher" than other filters (Pl. Resp. (Doc. 379), at 24-25), but the actual rates of these adverse events listed in the documents are extraordinarily small: 0.13% (for the 28 times higher allegation); 0.048%, 0.12%, 0.072%, and 0.158% (for the 4.6, 4.4, 4.1, and 5.3 times higher allegations); and 0.558% (for the 55 times higher allegation). The low reported adverse event rates for Bard's Recovery Filter should be viewed against the backdrop of medical literature that was publicly available for years before Dr. Lehmann's report, and which reported that all IVC filters are associated with numerous adverse events that occur at rates orders of magnitude higher than the reported rates for the Recovery Filter. (*See* Ex. E, Grassi, at Tables 1 and 2 (reported rate for death associated with all IVC filters 0.12%; reported rate for movement of IVC filters to the heart or lungs

---

2013 settlement involving a Bard subsidiary that is not part of this MDL and where the settlement agreement specifically denies any admission of liability. (*Id.*) Even if the plaintiffs' references to these issues had any merit, the crime-fraud exception does not apply to past conduct. *U.S. v. Zolin*, 491 U.S. 554, 562-63 (1989).

2-5%; reported rate for fracture associated with all IVC filters 2-10%; reported rate for migration associated with all IVC filters 0-18%; reported rate for IVC perforation associated with all IVC filters 0-41%).

The plaintiffs then claim that Bard failed to disclose information to the FDA, but the MAUDE database, which is the database that is the subject of Dr. Lehmann's analysis, is an FDA database. Thus, every adverse event that comprises Dr. Lehmann's analysis came from data that had previously been reported to the FDA. (Ex. S to Mot., Lehmann Report, at 1.) Moreover, in October 2004, Bard provided the FDA with reported adverse event rates for the Recovery Filter based on its internal adverse event information and filter sales. (Ltr. from M. Edwards (Bard) to L. Kennell (FDA), Oct. 5, 2004, at BPV-15-01-00058114, attached as Exhibit F.)

The plaintiffs argue that based on the foregoing, Bard was required to recall the Recovery Filter and Bard violated several federal regulations and criminal statutes in failing to do so. (Pl. Resp. (Doc. 379), at 25.) The FDA, however, has never said or suggested that the Recovery Filter should be recalled, and the FDA had the Recovery Filter's reported adverse event rates. Indeed, the FDA would not even consider Dr. Lehmann's findings an "emerging signal," let alone data that would require a voluntary recall. Just days ago, FDA issued a Draft Guidance, which addresses the agency's desire to communicate emerging safety signals to the public only when they are based on "reliable data" and supported by "sufficient strength of evidence." (FDA, Draft Public Notification of Emerging Postmarket Medical Device Signals, Dec. 31, 2015, at 5, 6, attached as Exhibit G.) But the FDA does not consider MAUDE database analysis "reliable data," and specifically warns that "MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrences across devices." (Ex. B, FDA MAUDE Disclaimer.) Thus, the plaintiffs' assertion that an analysis of MAUDE data constitutes a violation of federal law or requires a voluntary recall is without merit.

The plaintiffs have not proven by a preponderance of the evidence that Dr.

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000

Lehmann's report was "sufficiently related to" and "in furtherance of" a fraud. Even if the plaintiffs somehow have met their burden of proving that Bard was engaged in a seven-year-long fraud, the plaintiffs neither explain nor cite to anything to support the position that Dr. Lehmann's report was conceived of and created in furtherance of such a fraud. Rather, the plaintiffs cite only Exhibit 2 to their response brief, which is an e-mail that Dr. Lehmann wrote in April 2004 when he was serving as interim medical director at Bard and in which he was commenting on a single migration adverse event. (Pl. Resp. (Doc. 379), at 25.) The e-mail has nothing to do with the genesis of Dr. Lehmann's report eight months later in December 2004. In a footnote, the plaintiffs also argue that Dr. Lehmann's report "provided the statistical and analytical foundation of all of Bard's public and legal defenses to criticism of the Recovery Filter, public and legal defenses that the Report itself calls into question. A document more closely tied to Bard's criminal and fraudulent scheme is difficult to envision." (Pl. Resp. (Doc. 379), at 25 n.17.) The plaintiffs' cite nothing to support their argument, however. And the plaintiffs' argument is entirely inconsistent with other arguments made throughout their response brief.[12] Accordingly, the plaintiffs fail to meet their burden that Dr. Lehmann's report was sufficiently related to and created in furtherance of a fraudulent scheme.

c. Preserving a work-product claim does not require both a work-product objection and a confidentiality objection.

In arguing that Bard waived its work-product claim by failing to immediately object on work product *and* confidentiality grounds during the *Phillips* trial, the plaintiffs cite no case that required a confidentiality objection, and they selectively cite this Court's *Bickler* decision in their argument. In *Bickler*, this Court noted that "Courts have

[12] For instance, rather than being created in furtherance of a fraudulent scheme, the plaintiffs argue throughout their briefing that federal regulations required Bard to prepare Dr. Lehmann's report. (Pl. Resp. (Doc. 379), at 5-6). Rather than being a beneficial document to Bard, the plaintiffs argue that Bard was trying to "cover up Dr. Lehmann's findings" because he was preparing a report that would compile "bad information in a summary format." (*Id.* at 9.) The plaintiffs argue elsewhere in their brief that "there is no evidence that the Report was contemplated or used for any litigation purpose during the 11-plus years since its creation" (*id.* at 12), but the plaintiffs' new argument is that all of Bard's legal defenses are founded on Dr. Lehmann's report.

recognized that work product protection may be lost when the disclosure substantially increases the opportunity for potential adversaries to obtain the information, but they also have been willing to preserve the work product protection over documents in circumstances where the disclosure to a potential adversary was compelled." 266 F.R.D. 379, 384 (D. Ariz. 2010) (quotation omitted). This Court said nothing about requiring an additional objection on confidentiality grounds. Moreover, at the conclusion of the *Phillips* trial, Bard moved to seal Dr. Lehmann's report and several other trial exhibits, none of which were available on the public docket before Bard filed its motion to seal. Thus, the plaintiffs' argument fails for multiple reasons.

3. <u>The plaintiffs have no substantial need for Dr. Lehmann's report.</u>

The plaintiffs have not met their burden of proof of making a "special showing" that they have a "substantial need" for Dr. Lehmann's report and an "undue hardship" in obtaining "substantially equivalent" material by other means. Thus, they cannot overcome Bard's work-product protection for Dr. Lehmann's report.

Indeed, the plaintiffs admit that they have the same data that Dr. Lehmann had (Pl. Resp. (Doc. 379), at 28 ("Yes Plaintiffs can analyze the same data Dr. Lehmann did"). And they admit that their attorneys have had an expert purportedly perform the same analysis that Dr. Lehmann performed. (*Id.* (plaintiffs "even hired experts to do the same work"). Despite these admissions, the plaintiffs claim that they have substantial need for Dr. Lehmann's report because "Bard repeatedly touted Dr. Lehmann as an independent consultant" and "[t]reating physicians should be entitled to know, when deposed, what Bard knew at the time in the manner that Bard learned it—from an independent medical consultant."[13] (*Id.* at 27.) But Dr. Lehmann's report does not say that Dr. Lehmann is an "independent consultant"; rather, several non-privileged documents that the plaintiffs already have, such as the January 2005 Remedial Action Plan and December 2004 HHE, refer to Dr. Lehmann's report as an "independent study" by an "independent consultant,"

[13] The Court should also note that the plaintiffs' claim that "Bard has historically defended these cases by blaming physicians" is absolutely untrue, and the plaintiffs have cited nothing to support their position. (Pl. Resp. (Doc. 379), at 28.)

Snell & Wilmer L.L.P. LAW OFFICES One Arizona Center, 400 E. Van Buren, Suite 1900 Phoenix, Arizona 85004-2202 602.382.6000

and the "independent consultant's report." (Ex. 13 to Pl. Resp. (which contains multiple documents) at BPVE-01-01019777, 779, 781, 821.) Thus, these non-privileged documents provide exactly what the plaintiffs demand while Dr. Lehmann's report does not.

The plaintiffs argue that they will waste days of trial and resources to prepare an expert, defend "the inevitable" *Daubert* challenge, and put up an expert at trial to discuss Dr. Lehmann's findings. (Pl. Resp. (Doc. 379), at 28.) The plaintiffs' claim is speculative, however. Moreover, during the *Phillips* trial, Dr. Michael Freeman, the expert who purportedly performed the same analysis as Dr. Lehmann, testified and was cross examined for less than an hour and a half. (*Phillips v. C. R. Bard, Inc.*, 3:12-cv-00344-RCJ-WGC, Docket Entry 294 ("(1:39 p.m. - 2:59 p.m.) MICHAEL FREEMAN, MedDr., Ph.D., M.P.H. is called to the stand on behalf of the Plaintiff. The witness is sworn and testifies on direct and redirect examination by Mr. Troy Brenes; cross by Mr. Richard North, then excused"), attached as Exhibit H.) And, if the plaintiffs think that they are burdened in hiring an expert, they are free to use other discoverable material to prosecute their case, such as Dr. Ciavarella's December 17, 2004, HHE or the January 5, 2005, Remedial Action Plan, both of which the plaintiffs submitted as exhibits to their response brief and other courts have identified as substantially equivalent information to Dr. Lehmann's report. (Ex. 13 to Pl. Resp.)

Finally, the plaintiffs argue that it would be unfair to allow Bard to use the contents of Dr. Lehmann's report at trial. (Pl. Resp. (Doc. 379), at 28.) Again, the plaintiffs' claim is speculative, and in the history of this litigation, Bard has not relied on Dr. Lehmann's report in its defenses.

For each of these reasons, and as further detailed in Bard's Motion, every court to address the plaintiffs' substantial need argument has rejected it and found that the plaintiffs have numerous alternative sources of substantially equivalent information. (Mot. (Doc. 306), at 13-14.)

4. <u>No additional discovery or evidentiary hearing is needed.</u>

Neither the plaintiffs nor Bard have identified a single case with a more robust

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000

record than this case concerning the genesis of a single document. Moreover, the plaintiffs have not identified a single case to support their position that even more discovery is warranted. Finally, the plaintiffs are calling for some discovery that they already have (i.e., prior contracts with Dr. Lehmann and Bard's actions surrounding MAUDE data) and discovery of material that would be protected work product (i.e., drafts of Dr. Lehmann's report and time records concerning his December 2004 report). As discussed in Bard's Motion, the record is more than sufficient to resolve Bard's motion without additional discovery.

CONCLUSION

For the foregoing reasons, and as further discussed in Bard's Motion for Protective Order, the Court should grant Bard's Motion, and find that Dr. Lehmann's report is protected work product without exception or waiver. The Court should also decline to allow additional discovery or to hold another evidentiary hearing. Finally, the Court should apply its ruling only to cases in which the protection of Dr. Lehmann's report has not previously been decided.

DATED this 8th day of January, 2016.

SNELL & WILMER L.L.P.

By: s/Amanda C. Sheridan

James R. Condo
Amanda C. Sheridan
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
Nelson Mullins Riley & Scarborough LLP
201 17th Street, NW / Suite 1700
Atlanta, GA 30363

Attorneys for C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000

CERTIFICATE OF SERVICE

I hereby certify that on January 8, 2016, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Amanda C. Sheridan

23282526

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000